NAME: ILISA BERNSTEIN, PHARM.D., J.D.

JOB TITLE: DIRECTOR OF PHARMACY AFFAIRS

AGENCY: FOOD AND DRUG ADMINISTRATION
OFFICE OF THE COMMISSIONER,
OFFICE OF POLICY

EDUCATION/DEGREES/CERTIFICATES/INSTITUTIONS:

Dr. Ilisa Bernstein received her Doctor of Pharmacy from University of Michigan in 1987, followed by a residency at National Institutes of Health (NIH) in Bethesda, Maryland. After completing her residency, she took a job with the Food and Drug Administration (FDA) as a Pharmacokinetic Reviewer in the Division of Biopharmaceutics. While working at the FDA, she obtained her Juris Doctor degree at the American University – Washington College of Law evening program.

CURRENT JOB DESCRIPTION:

Dr. Bernstein advises the Commissioner, Deputy Commissioner for Policy, and FDA senior management on domestic and international issues related to the regulation of medical products (i.e. drugs, biologics, dietary supplements, medical devices, and other pharmacy-related issues). In this role, she develops and evaluates Agency policies and initiatives, provides policy analyses on issues, drafts regulations, policy statements, guidances, and special reports, and prepares speeches, testimony, articles, and briefing materials for the Commissioner and other FDA officials. Her primary focus is on the U.S. drug distribution system, counterfeit drugs, drug importation, advertising and promotion, prescription and OTC drug labeling, the drug approval process, and internet matters. She also serves as the primary liaison between FDA and pharmacy organizations often participating in and helping to organize public FDA meetings.

Dr. Bernstein has chaired many of the working groups of which she has also been a member. She was instrumental in developing and implementing the policy for FDA's Counterfeit Drug Task Force, whose goal is to further secure the U.S. drug supply. She played a major role in developing the Health and Human Services Drug Importation Task Force Report, which outlines various legal, regulatory, safety, and economic issues related to drug importation. She led the Drug Facts Working Group, which significantly improved the content and format of OTC drug product labeling, and the Intra-Agency Working Group on Advertising and Promotion, which developed Direct-to-Consumer promotion policies, the Medication Guide Rule, consumer information initiatives, and off-label use policies. She chaired the Internet Working Group, which addressed use of the internet for advertising, promotion, and sale of drugs. She also chaired the Tobacco/Cigarette Petition Working Group, which led to initiatives aimed at regulating nicotine-containing products.

In addition, Dr. Bernstein has led or participated in a variety of other task forces and working groups focused on all aspects of the drug development and approval process, prescription and OTC labeling, patient education and patient labeling, OTC drug issues, and dietary supplements.

Dr. Bernstein also serves as preceptor/supervisor to pharmacy, medical and law students, and management interns.

QUALIFYING SKILLS FOR CURRENT POSITION:

Dr. Bernstein worked at the Agency for fourteen years (3 years as a pharmacokinetic reviewer and 11 years as a policy advisor) before taking a job with a large pharmaceutical firm as a Senior Associate Director. She provided advice to senior management and drug project teams, and optimized regulatory approaches for product development and approval. She also developed corporate policies governing global clinical research and development, and provided analyses of FDA regulations, policies, and legislation and their impact on corporate operations; however, Dr. Bernstein missed the challenging work at the FDA. She decided to return to the Agency after 18 months away, and accepted a position with the Office of the Commissioner.

MOST REWARDING USPHS PROFESSIONAL EXPERIENCE:

Dr. Bernstein works on long term projects and often doesn't see the results of these projects for years. For example, she worked on the Drug Facts over-the-counter drugs labeling project and it took over four years to complete from the proposed rule to the final rule. Being involved in such a large project from start-to-finish gave her a truly rewarding sense of accomplishment.

OTHER PROFESSIONAL ACTIVITIES:

Fellow, American Society for Pharmacy Law (ASPL) (1998-present)
Delegate, APhA House of Delegates (1990-95, 97-present)
Chair, APhA New Business Policy Committee (2003-2004)
Chair, Publications and Scholarship Committee, ASPL (2001-2003)
Board of Directors, ASPL (1998-2001)
USPHS Pharmacy Professional Advisory Committee (1995-1998)
Chair, APhA Policy Committee and Reference Committee (1997-1998)
The Food and Drug Law Institute (Meeting Planning Committee) (1995-1996)
ASPL Washington D.C. Planning Committee (1995-1996)
Vice Chair, APhA Policy Committee (Scientific Affairs) (1990, 1994)
APhA Policy Committee (Member) (Scientific & Public Affairs) (1989, 1993)
APhA Reference Committee (Scientific Affairs) (1991, 1995)
APhA Strategic Planning Committee on Awards (1985-1986)

SPECIAL NOTES OF INTEREST:

Dr. Bernstein is an Adjunct Clinical Assistant Professor at the University of Michigan. She is also a co-author of Pharmacy Law Digest, a textbook on pharmacy law that is used in pharmacy schools across the nation.